# FEB 0 9 2007

USSN: 09/554,533 Atty. Docket No. 238/086 US

#### REMARKS

### Status of Claims

Claims 55-75 are pending. Claims 55-62, 66-71, and 74-75 are under consideration by the Examiner. Claims 63-65 and 72-73 are withdrawn from consideration.

### New Objections to claims

The Examiner has objected to claims 55-62, 66-71 and 74-75 for disclosing a peptide formula in claims 55 and 66 without a SEQ ID NO. Applicants submit that this objection is most in view of the amendment to the claims.

The Examiner has also objected to claims 56, 58, 61, 66-69 and 74-75 for containing nonelected subject matter. However, previously, the Examiner had indicated the claims were being
considered for examination. Further, the Examiner does not indicate these claims are withdrawn
from consideration in the first page of the office action and has considered the claims in the
rejections provided in the Office Action. Applicants request that this objection be withdrawn as
the Examiner has clearly searched the subject matter of the claims and therefore there is no
additional burden on the Examiner to continue prosecution of these claims. Applicants direct the
Examiner's attention to MPEP § 803 that states "if search and examination of all of the claims in
an application can be made without serious burden, the Examiner must examine them on the
merits, even though they include claims to independent or distinct inventions" (emphasis added).
In the alternative, Applicants request that this objection be held in abeyance until allowable
subject matter is indicated.

#### Rejection of Claims Under 35 U.S.C. § 101

Claims 55-62, 66-71, and 74-75 stand rejected by the Examiner because they cover a naturally-occurring peptide or polypeptide. Applicants traverse the rejection and maintain that it is incumbent on the Examiner to show that the peptides claimed are naturally occurring. It is axiomatic that the Patent Office has the initial burden to present a prima facie case of unpatentability. The Examiner's assertion that the peptide "might exist naturally" is wholly insufficient to present a prima facie case. The Examiner has essentially admitted he has no concrete basis for the rejection by improperly attempting to shift the burden to applicant.

PAGE 08

USSN: 09/554,533 Atty. Docket No. 238/086 US

However, solely to expedite prosecution of the application, Applicants have amended the claims to recite "isolated peptide compounds." Accordingly, Applicants submit that the rejection is most and should be withdrawn.

## Rejection of Claims Under 35 U.S.C. § 102(e)

Claims 55, 57, 59-60, 62, 66, 69-70 and 74 are rejected under 35 U.S.C. § 102(e) as being anticipate by Beeley et al. (U.S. Patent No. 6,956,026B2) ("Beeley").

Applicants respectfully traverse the rejection. Beeley is not properly prior art to the instant application because the sequences claimed in the instant application are not disclosed in the priority documents identified in Beeley, i.e., the sequences are not disclosed in either Provisional Application Serial No. 60/034,905 filed January 7, 1997 or in Provisional Application Serial No. 60/055,404 filed on August 8, 1997. Thus, in regards to the claimed sequences, Beeley has an effective filing date after the priority date of the present application.

Accordingly, the rejection is improper for at least this reason and should be reconsidered and withdrawn.

### Rejection of Claims Under 35 U.S.C. § 103(a)

The Examiner has rejected claims 55-62, 66-70 and 74 under 35 U.S.C. § 103(a) as being unpatentable over Beeley et al. The Examiner acknowledges that Beeley does not disclose a peptide where Xaa<sub>2</sub> is Ser and Xaa<sub>14</sub> is Leu or where Xaa<sub>2</sub> and Xaa<sub>3</sub> are Ser and Asp, respectively, but asserts that such modifications would be obvious. However, the Examiner provides no basis for this conclusion other than to assert that one might try to make such modifications. Notwithstanding that "obvious to try" is not the standard of 35 USC 103, (see, e.g., In re Tomlinson, 53 CCPA 1421, 363 F.2d 928, 150 USPQ 623 (1966); In re Dien, 54 CCPA 1027, 371 F.2d 886, 152 USPQ 550 (1967) and In re Wiggins, 55 CCPA 1356, 397 F.2d 356, 158 USPQ 199 (1968), and In re Saether, 492 F.2d 849, 181 USPQ 36 (CCPA 1974)) and that the Examiner has not established a prima facie case of obviousness, as noted above, Beeley is not properly prior art to the instant application. Therefore, for at least these reasons, the rejection is improper and should be reconsidered and withdrawn.

# FEB 0 9 2007

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### Conclusion

In view of the foregoing arguments and amendments, each of the presently pending claims is believed to be in immediate condition for allowance. All of the stated grounds of rejection or objection have been traversed, accommodated, or rendered moot. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and objections and to pass this application to issue.

With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicants believe that the present application is now in condition for allowance. The Examiner is encouraged to call the undersigned to discuss any issues related to the prosecution of the instant application.

The Commissioner is hereby authorized to charge payment of any fees associated with this communication, to Applicant's Deposit Account No. 010535 referencing Docket No. 238/086-US. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Applicant's Deposit Account No. 010535.

> Respectfully submitted, AMYLIN PHARMACEUTICALS, INC.

Dated:

9-Feb-07

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